

### REMARKS

This Amendment is submitted in response to the Office Action mailed on November 3, 2003. Claims 1-18 are originally pending, claims 4-7 and 10-14 have been cancelled, claims 1-3, 8, and 15-18 have been amended, and claims 19-28 are new. In view of the foregoing amendments, as well as the following remarks, Applicants respectfully submit that this application is in complete condition for allowance and request reconsideration of the application in this regard.

#### Rejections of Claims Under 35 U.S.C. § 102

Claims 8, 9 and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,370,983 (Lichtenstein). Of the rejected claims, claims 8 and 16 are independent claims. The Examiner contends that Lichtenstein shows or teaches all the elements of the rejected claims, which is an absolute requirement for anticipation under 35 U.S.C. § 102. Applicants respectfully disagree for the reasons set forth below.

Claim 8 is directed to a pump control system in which the controller uses "an adaptive law to generate a set of controller parameters for correcting time-dependent deviations of the flow rate from a predetermined flow rate" and "a control law to generate the output signal from the set of controller parameters for adjusting the pumping rate of fluid." Lichtenstein discloses a microcomputer-based system that calculates an ultrafiltration rate based upon flow meter readings and that measures total flow by time-integrating the ultrafiltration rate (Column 13, lines 17-37). In contrast to Applicants' claim 8, Lichtenstein does not teach, disclose or

suggest a controller that uses an adaptive law to generate a set of controller parameters for adjusting the pumping rate of fluid generated by a pump in a hemofiltration system. Moreover, Lichtenstein does not teach, disclose or suggest a controller that uses a control law to generate an output signal from the set of controller parameters for adjusting the liquid pumping rate. In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. As Lichtenstein fails to teach a controller having an adaptive law that generates a set of controller parameters for adjusting the pumping rate of fluid generated by at least one pump and a control law that generates an output signal from the controller parameters for adjusting pumping rate, Lichtenstein does not anticipate independent claim 8. For at least these reasons, Applicants respectfully request that this rejection be withdrawn.

Because claim 9 depends from independent claim 8, Applicants submit that claim 9 is also patentable for at least the same reasons discussed above. Furthermore, claim 9 recites a unique combination of elements not taught, disclosed or suggested by Lichtenstein.

Independent claim 16 is patentable for at least the same reasons as claim 8, as addressed in the preceding remarks by the Applicants regarding claim 8. Specifically, Lichtenstein fails to teach a controller having an adaptive law that generates a set of controller parameters for adjusting the pumping rate of fluid generated by at least one pump and a control law that generates an output signal from the controller parameters for adjusting pumping rate. For at least this reason, Applicants submit that claim 16 is patentable and request that the rejection be withdrawn.

**Rejections of Claims Under 35 U.S.C. § 103**

Claims 1-3 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lichtenstein in view of U.S. Patent No. 5,503,624 (Roeher et al.). Of the rejected claims, claims 1 and 15 are independent claims. Claim 1 recites that the controller analyzes "the flow rate data signals and the patient parameter data signals utilizing fuzzy logic based on at least one predetermined supervisory rule." The Examiner concedes that Lichtenstein does not disclose fuzzy logic control based upon monitoring patient parameters and system parameters of pressure and flows. The Examiner contends that it would have been obvious to one of ordinary skill in the art to modify the controller of Lichtenstein with the fuzzy logic control of Roeher et al. Applicants respectfully disagree for the reasons set forth below.

Roeher et al. is not concerned with preventing the development of an undesirable physiology by regulating the flow rate of a liquid selected from infusate, drained fluid, and blood in the hemofiltration system. Instead, Roeher et al. teaches a reactionary approach to a patient parameter deviation based upon drug infusion. Specifically, Roeher et al. relies on fuzzy logic for determining automatic dosing of drugs to attempt to compensate for a deviation in a patient parameter. See Roeher, Abstract; col. 4, lines 19-22. In other words, the infusion system of Roeher et al. is not configured for controlling the flow rate of a liquid selected from the group consisting of infusate, drained fluid, and blood generated by a pump in a hemofiltration system for regulating fluid removal from a patient's blood. Roeher et al. does not appreciate that fluid removal may be regulated by controlling the flow rate of a liquid in the hemofiltration system. One of ordinary skill in the art would not modify the medical care system of Lichtenstein with the fuzzy logic of Roeher et al. because Roeher et al. is not concerned with controlling the

pumping rate of either infusate, drained fluid, or blood to prevent the occurrence of an undesirable physiology.

The Examiner has failed to provide a suggestion or motivation to combine Lichtenstein with Roher et al. As such, the Examiner has failed to establish a *prima facie* case of obviousness. For at least this reason, Applicants submit that claim 1 is patentable and that the rejection of claim 1 should be withdrawn.

Assuming, *arguendo*, that one combined Lichtenstein with Roher et al., the resulting system would not include all elements of claim 1. As discussed above, Roher et al. does not disclose or suggest that the controller uses fuzzy logic to control the flow rate of liquid from a pump pumping a liquid selected from the group consisting of infusate, drained fluid, and blood. Consequently, even if the two references were combined, the resulting system would not include every element of claim 1. For at least this reason, Applicants submit that claim 1 is allowable and that the rejection should be withdrawn.

As claims 2 and 3 depend from independent claim 1, Applicants submit that these claims are also patentable for at least the same reasons. These claims also recite unique combinations of elements not taught, disclosed or suggested by Lichtenstein as modified by Roher et al.

Independent claim 15 is patentable for at least the same reasons as claim 1, as addressed in the preceding remarks by the Applicant regarding claim 1. Specifically, Roher et al. does not disclose or suggest that the controller uses fuzzy logic to control the flow rate of liquid from a pump pumping a liquid selected from the group consisting of infusate, drained

fluid, and blood. For at least this reason, Applicant submits that claim 15 is patentable and requests that the rejection be withdrawn.

Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable Lichtenstein in view of U.S. Patent No. 5,211,849 (Kitaevich et al.). Applicant incorporates by reference the discussion provided above with respect to independent claim 8. Moreover, Kitaevich et al. fails to cure the deficiencies of the Lichtenstein reference. Furthermore, claim 18 recites a unique combination of elements not taught, disclosed or suggested by the combination of Lichtenstein and Kitaevich et al. Even if the two references were combined, the resulting system would not include every element of claim 18. As the Examiner has failed to support a *prima facie* case of obviousness, Applicants submit that independent claim 18 is patentable for at least the same reasons as independent claim 1 and request that the rejection be withdrawn.

Claim 17 stands rejected under 35 U.S.C. § 103(a) as being unpatentable Lichtenstein in view Roher et al. and Kitaevich et al. Applicant incorporates by reference the discussion provided above with respect to independent claim 1. Moreover, Kitaevich et al. fails to cure the deficiencies of the Lichtenstein and Roher et al. references. Furthermore, claim 17 recites a unique combination of elements not taught, disclosed or suggested by the combination of Lichtenstein, Roher et al. and Kitaevich et al. Even if the references were combined as suggested by the Examiner, the resulting system would not include every element of claim 17. As the Examiner has failed to support a *prima facie* case of obviousness, Applicants submit that independent claim 17 is patentable for at least the same reasons as independent claim 1 and request that the rejection be withdrawn.

Claims 19-28 have been submitted as new claims in which the combinations of recited elements are neither disclosed nor suggested by the art of record.

### CONCLUSION

Applicants have made a bona fide effort to respond to each and every requirement set forth in the Office Action. In the event that any issues remain outstanding, the Examiner is invited to contact the undersigned to expedite issuance of this application.

Applicants do not believe fees are dues in connection with filing this communication. If, however, additional fees are necessary as a result of this communication, the Commissioner is hereby authorized to charge any under-payment or fees associated with this communication or credit any over-payment to Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

By: \_\_\_\_\_

*William R. Allen*

William R. Allen, Ph.D.

Reg. No. 48,389

2700 Carew Tower  
Cincinnati, Ohio 45202  
(513) 241-2324